

visual change.

31. A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy by detecting the presence of amniotic fluid outside the amnion, the method comprising:

applying to a surface which is suspected to have amniotic fluid a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid having a pH in the range of amniotic fluid, said pH-sensitive material being selected from the group consisting of a solid, a liquid, and a gel, and said pH-sensitive material being non-irritating to the woman.

REMARKS

The present amendment is in response to the Office Action mailed April 25, 2002, in which claims 1-17 and 31-34 were rejected. Applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the reference cited therein. The following remarks are believed to be fully responsive to the Office Action and, when coupled with the amendments made herein, are believed to render all claims at issue patentably distinguishable over the cited reference.

Claims 1, 6, 12 and 17 have been canceled. No claims are added. Accordingly, claims 2-5, 7-11, 13-17 and 31-34 are presently pending in the application. Claims 2, 7 and 13 have been amended to incorporate the limitation of claims 6, 12 and 17, respectively. Claim 31 has been amended to incorporate the same limitation to that added to claim 2.

All the changes are made for clarification and are based on the application and drawings as originally filed. It is respectfully submitted that no new matter is added.

Applicants respectfully request reconsideration in light of the above amendments and the following remarks.

Double Patenting Rejection

Claims 1 and 13-17 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,126,597. Claims 1 and 13-17 also stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of co-pending Application No. 09/793,722.

Applicants hereby file terminal disclaimer in compliance with 37 CFR 1.321(c), which is signed by attorney of record.

Accordingly, the provisional and actual double patenting rejection are moot.

Rejection under 35 U.S.C. §102

Claims 1-17 and 31-34 stand rejected under 35 U.S.C. §102 as being anticipated by Yazaki JP 5-123324. Applicants respectfully reverse this rejection.

To anticipate a claim, the reference must teach every element of the claim. “The identical invention must be shown in as complete detail as is contained in the ... claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Yazaki teaches a pad for determining amniorrhexis. The pad comprises an absorbing body 2, an unwoven cloth 3 which wraps the absorbing body 2, a watertight laminate paper 4, an unwoven cloth 5 which wraps around the laminate paper 4, and a pH indication agent sheet 6.

The watertight laminate paper 4 wraps around the unwoven cloth 3 except the middle part of top surface of the cloth 3. Thus, the cloth 3 is exposed at its top surface portion. The pH indication agent sheet 6 is comprised of a sheet 7 which is wet with bromthymol blue (BTB) and placed on the exposed surface of the cloth 3 and between the unwoven cloth and the unwoven cloth 5. Thus, the sheet 6 is placed underneath the unwoven cloth 5 and, thus, will not be brought to contact to the skin of a wearer.

Conversely, the claimed system and method do not have a sheet that is impregnated with a pH indicating material and covered with extra layer of cloth. For the present invention, a pH-sensitive material is applied to the surface of an article, which is for wearing substantially adjacent the crotch of a pregnant woman. Thus, according to the invention, the pH-sensitive material will be in direct contact with the skin of the woman or is applied to the skin of the woman, which renders a more precise and accurate determination of the amniorrhexis.

Thus, Yazaki fails to teach or suggest every element of the claims.

Therefore, it is respectfully requested that the rejection based on 35 U.S.C. §102 be withdrawn in light of the amendment and foregoing remarks.


Attached hereto is a marked-up version of the changes made to the specification and abstract by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

CONCLUSION

Applicants submit that the present application is now in condition for allowance. Early notice of such action is earnestly solicited and will be greatly appreciated. If any outstanding issues remain, the Examiner is invited to contact the undersigned attorney at 202-624-3947 in an effort to resolve any matter still outstanding before issuing another action. The undersigned attorney is confident that any possible remaining issues can readily be worked out by telephone.

Favorable reconsideration is respectfully requested.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 1, 6, 12 and 17 are canceled.

Claim 2 is amended as follows:

2. (Amended) A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy, the method comprising the sequential steps of:

forming an article for wearing substantially adjacent the crotch of the pregnant woman;

applying to said article a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid with a pH in the range of amniotic fluid, said pH-sensitive material being non-irritating to the woman and having a readily applicable form, said form being selected from the group consisting of liquid drops, atomized spray, aerosol liquid, powder, gel, and a solid;

wearing said article for a period of time; and

visualizing said pH-sensitive material for a visible change

Claim 7 is amended as follows:

7. (Amended) A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy, the method comprising the sequential steps of:

forming an article for wearing substantially adjacent the crotch of the pregnant woman;

wearing said article for a period of time;

applying to said article a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid with a pH in the range of amniotic fluid, said pH-sensitive material being non-irritating to the woman; and

visualizing said pH-sensitive material for a visible change.

Claim 13 is amended as follows:

13. (Amended) A system for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy by detecting the presence of amniotic fluid outside the amnion, the system comprising:

an article for wearing substantially adjacent the crotch of a pregnant woman; and

a pH-sensitive material capable of responding by way of a visible change to the presence of fluid with a pH in the range of amniotic fluid, said material being applicable by the woman to said article prior to said article being worn, the pH-sensitive material being non-irritating to the woman and having a form selected from the group consisting of liquid drops, an atomized spray, an aerosol liquid, a powder, a gel, and a solid:

whereby the woman visualizes said article after wearing said article to observe a visual change.

Claim 31 is amended as follows:

31. (Amended) A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy by detecting the presence of amniotic fluid outside the amnion, the method comprising:

applying to a surface which is suspected to have amniotic fluid a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid having a pH in the range of amniotic fluid, said pH-sensitive material being selected from the group consisting of a solid, a liquid, and a gel, and said pH-sensitive material being non-irritating to the woman.